

**PATENT APPLICATION****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of

Docket No: Q64175

Kenichiro SHIROYAMA, et al.

Appln. No.: 09/848,225

Group Art Unit: 1615

Confirmation No.: 6389

Examiner: CHANNAVAJJALA, Lakshmi Sarada

Filed: May 4, 2001

For: **CLEAR AQUEOUS CERAMIDE COMPOSITION****DECLARATION UNDER 37 C.F.R. § 1.132**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

I, Kenichiro Shiroyama, hereby declare and state:

I graduated from Kanagawa University, Faculty of Technology, Department of Applied Chemistry in March of 1980.

Since April of 1980, I was employed by the Milot Co., Ltd.

Since 1994, I have been employed by the Takasago International Corporation, the assignee of the present application.

Since April of 1980, I have been engaged in research and development on fragrances.

I reviewed the Official Action of January 13, 2006, which issued in the present application, and am well aware of the rejections therein and have studied all of the prior art relied upon by the Examiner, the specification of the present application and the claims of the present application.

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I have performed or had performed under my direction and control certain experimentation to establish the criticality of choosing the appropriate temperature for heating the carrier components, i.e., non-ionic surfactants, amphoteric surfactants, etc., in order to provide an efficient carrier for lipophilic components such as ceramides as the Examiner has required in the material bridging pages 4/5 of the Official Action of January 13, 2006, which experimentation is now set forth.

**Experimental Results**

The compositions of Examples 1 to 8 of the present invention were prepared. Then, the pH of each composition was measured.

**EXAMPLES 1 TO 5**

Components 1 to 6 shown in Table 1 were uniformly mixed while heating at 80 to 120°C. Components 7 to 8 which had been heated to 80 to 120°C were mixed with the mixture of components 1 to 6 while heating to prepare a lipid composition. Component 9 (purified water) which had been heated to 80 to 100°C was slowly added to the lipid composition and mixed uniformly therewith to prepare aqueous compositions. The proportions shown in Table 1 are given by percent by weight, and "q.s. (quantum sufficit)" means an amount sufficient to make up 100% by weight (the same applies to other Tables hereinafter given).

The compositions thus prepared were allowed to stand at room temperature for 1 month, at 40°C for 2 weeks, and at 5°C for 2 weeks in this order, and the appearance thereof was

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observed with the naked eye and these compositions were rated A to E according to the following rating system. The results obtained are shown in Table 1.

A ... Clear

B ... Almost clear

C ... Slightly white-turbid

D ... White-turbid

E ... Precipitates observed.

TABLE 1

Component	Example 1	Example 2	Example 3	Example 4	Example 5
1. Optically active ceramide (a)*	1.50	3.00	1.00	1.00	1.00
2. Isostearic acid	1.50	2.00	1.00	-	0.50
3. Oleic acid	-	-	-	0.50	-
4. Cholesterol	-	-	-	-	0.50
5. POE (60)** hydrogenated castor oil	8.00	15.00	5.00	5.00	3.25
6. POE (20)** sorbitan monooleate	-	-	-	-	1.75
7. 1,3-Butylene glycol	-	10.00	10.00	5.00	10.00
8. Concentrated glycerin	-	-	-	5.00	10.00
9. Purified water	q.s.	q.s.	q.s.	q.s.	q.s.
Appearance	A	B	A	A	A
pH	<u>7.2</u>	<u>7.2</u>	<u>7.2</u>	<u>7.2</u>	<u>7.2</u>

Note: \* Optically active ceramide (a): (2S,3R)-2-Octadecanoylaminoctadecane-1,3-diol  
(hereinafter the same)

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\*\* The number in the parentheses indicates the number of repeating ethylene oxide units (hereinafter the same).

**COMPARATIVE EXAMPLES 1 TO 3**

Clear aqueous compositions were prepared from the components shown in Table 2 below in the same manner as in Examples 1 to 5 in the present application. The stability of the compositions was evaluated in the same manner as in Examples 1 to 5 which was the same as for the results in Table 1. The results are shown in Table 2.

TABLE 2

Component	Compara. Example 1	Compara. Example 2	Compara. Example 3
1. Optically active ceramide (a)	2.00	-	1.00
2. Isostearic acid	2.00	2.00	1.00
3. Oleic acid	-	-	-
4. Cholesterol	-	2.00	-
5. POE (60) hydrogenated castor oil	-	6.00	-
6. POE (20) sorbitan monooleate	-	-	-
7. Sodium POE (4) lauryl ether phosphate	-	2.00	1.00
8. Glycerin solution containing 50% lecithin hydroxide	-	-	20.00
9. 1,3-Butylene glycol	-	10.00	-
10. Concentrated glycerin	-	-	20.00
11. Purified water	q.s.	q.s.	q.s.
Appearance	E	C	E
pH	7.1	10.5	10.4

It can be seen from the results in Tables 1 and 2 that the compositions of Examples 1 to 5 have excellent stability over a broad temperature range, whereas the compositions of the Comparative Examples are less stable, failing to achieve satisfactory results.

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**EXAMPLES 6 TO 8 AND APPLICATION EXAMPLE 1**

Aqueous compositions were prepared from the components shown in Table 3 below in the same manner as in Examples 1 to 5 in the present application. The composition of Application Example 1 presents an example of a preparation containing an anionic surface active agent. The stability of the compositions was evaluated in the same manner as in Examples 1 to 5. The results are shown in Table 3.

TABLE 3

Component	Example 6	Example 7	Example 8	Appln. Example 1
1. Optically active ceramide (a)	2.00	-	1.00	2.00
2. Optically active ceramide (b)*	0.50	2.00	-	-
3. Racemic ceramide (c)**	-	-	1.00	-
4. Isostearic acid	2.00	2.00	2.00	2.00
5. Cholesterol	2.00	2.00	2.00	2.00
6. POE (60) hydrogenated castor oil	8.00	6.00	8.00	6.00
7. Sodium POE (4) lauryl ether phosphate	-	-	-	2.00
8. 1,3-Butylene glycol	10.00	10.00	10.00	10.00
9. Purified water	q.s.	q.s.	q.s.	q.s.
Appearance	A	A	A	A
pH	<u>7.1</u>	<u>7.3</u>	<u>7.2</u>	<u>10.6</u>

Note: \* (2S,3R)-2-(2-hydroxyhexadecanoyl)aminoctadecane-1,3-diol

\*\* 2-Octadecanoylaminoctadecane-1,3-diol

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From the fact that the composition of Comparative Example 2 (containing no ceramide) showed white turbidity whereas clear aqueous compositions were obtained in Application Example 1, which is the composition of Comparative Example 2 having a ceramide incorporated therein, and Examples 1 to 8, it is believed clear that the compositions of the present invention comprise a water-soluble lipid composite essentially composed of a ceramide.

Furthermore, as shown by the above results, since each composition of Examples 1 to 8 had a pH in the range of 7.1 to 7.3, which is nearly a neutral condition, the compositions of Examples 1 to 8 are friendly for skin and hair, i.e., they would not be irritating to the skin.

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: April 5, 2006

Kenichiro Shiroyama  
Kenichiro Shiroyama